REMARKS

The Office action mailed 20 March 2007, has been received and its contents carefully noted. Claims 16-22 were rejected. Claims 32-43 have been added. Support may be found in the specification and claims as originally filed. Reconsideration in view of the following remarks is respectfully requested.

Rejection under 35 U.S.C. 103(a)

The Examiner rejected claims 16-22 under 35 U.S.C. 103(a) as being unpatentable over Wolf et al., Accession #P53509 (P53509) in view of Wood and further in view of Wolf et al. (1989). Specifically, the Examiner deemed that P53509 teaches a signal sequence which would have been obvious to remove in view of Wood and that Wolf et al. (1989) discloses an agarose gel protein band at 16 kDa from CS6 compositions with which antisera was generated.

Applicants respectfully submit that a prima facie case of obviousness has not been established as P53509 can not be used as a proper prior art reference against the instant invention. Specifically, P53509 indicates that the sequence was submitted sometime in January 1994. P53509 indicates that the sequence information was *not* published (i.e. integrated into the database) and publicly available until 1 October 1996, which is over two years *after* the priority date (13 May 1994) of the present invention.

From the Swiss-Prot User Manual[1], it is indicated that:

> The DT (DaTe) lines show the date of creation and last modification of the database entry.
>
> The format of the DT line in Swiss-Prot is:
>
> DT DD-MMM-YYYY, integrated into UniProtKB/database_name.
> DT DD-MMM-YYYY, sequence version x.
> DT DD-MMM-YYYY, entry version x.
>
> Where 'DD' is the day, 'MMM' the month and 'YYYY' the year, respectively. The dates shown in DT lines correspond to the date of the biweekly release at which an entry was integrated or updated. There are always three DT lines in each entry, each of them is associated with a specific comment:
>
> - The first DT line indicates when the entry first appeared in the database. The associated comment, 'integrated into UniProtKB/database_name', indicates in which section of UniProtKB, Swiss-Prot or TrEMBL, the entry can be found;

1 The relevant portion of the Swiss-Prot User Manual may be found at http://ca.expasy.org/uniprot/P53509 and clicking on the heading entitled "Integrated into Swiss-Prot on". The prior versions can also be found using a link provided in the pop-up box that appears.

- The second DT line indicates when the sequence data was last modified. The associated comment, 'sequence version', indicates the sequence version number. The sequence version number of an entry is incremented by one when the amino acid sequence shown in the sequence record is modified;

- The third DT line indicates when data other than the sequence was last modified. The associated comment, 'entry version', indicates the entry version number. The entry version number is incremented by one whenever any data in the flat file representation of the entry is modified.

The DT lines for P53509 may be found at http://ca.expasy.org/cgi-bin/get-sprot-entry?P53509 and are as follows:

DT 01-OCT-1996, integrated into UniProtKB/Swiss-Prot.
DT 01-OCT-1996, sequence version 1.
DT 31-OCT-2006, entry version 20.

Therefore, Applicants respectfully submit that P53509 can not be used as a prior art reference against the claimed invention as it was not published or publicly available until 1 October 1996 which is after the effective filing date of the present invention. A copy of the original entry as was available on 1 October 1996 is attached herewith.

Applicants respectfully submit that the disclosure of Wolf et al. (1989), alone or in combination with Wood, does not result in the claimed invention. Specifically, the Examiner merely speculates that the protein at the 16 kDa band disclosed in Figure 3 of Wolf et al. (1989) is CssA. However, since the sequence of CssA was not known prior to the present invention and Wolf et al. (1989), alone or in combination with Wood, teach or suggest SEQ ID NO:9 (or SEQ ID NO:5), a prima facie case of obviousness has not been established.

Therefore, Applicants respectfully submit that the claimed invention is unobvious and the rejection under 35 U.S.C. 103(a) should properly be withdrawn.

Recapture of Previously Deleted Subject Matter

Applicants previously amended the claims to be limited to a polypeptide sequence consisting of SEQ ID NO:9 in order to avoid reading on P53509 which was, at the time, believed to be a proper prior art reference. However, since the last response, Applicants have found information which definitely indicates the date which P53509 became available as prior art. Thus, Applicants have amended claim 16 and added claims 32-43 to recapture subject matter to which they are entitled.

Rejection under 35 U.S.C. 102(b)/103(a)

The Examiner rejected claims 16-22 under 35 U.S.C. 102(b) as being anticipated by Wolf et al. (1989) or, in the alternative, under 35 U.S.C. 103(a). The Examiner indicates that although Wolf et al. does not disclose the sequence of a band of protein in a gel which was excised out and used to generate antisera, Wolf et al. inherently anticipates the claimed invention or renders the claimed invention obvious. Specifically, the Examiner points to the 16 kDa band in Figure 3 and related discussion in Wolf et al. for asserting that the protein in the 16 kDa band is a purified peptide inherently having SEQ ID NO:9.

Applicants respectfully submit that the Examiner's reasoning for disregarding Applicants' prior arguments is wrong. Specifically, the Examiner indicates on page 8 that Applicants arguments are not persuasive because:

> the protein would not be both CssA and CssB because each subunit is between ~15-16kDa and the single band is 16kDa (not 30-32kDa) so there would be no need to purify the two subunits from each other.

Applicants respectfully submit that the native CssA and native CssB subunits are not expressed as a fusion protein which would result in a protein band at about 30-32 kDa nor are Applicants asserting such. Instead, Applicants arguments are directed to the fact that CS6 comprises four (4) subunits, CssA, CssB, CssC and CssD. CssA and CssB have a molecular weight of 15,058 and 15,877 daltons, respectfully. Since the molecular weights of CssA and CssB are similar, the two proteins would both elute as separate proteins (not as a fusion protein) in a gel at a band of around 16 kDa.

The Examiner appears to make an inherency type of rejection by stating that the protein at the 16 kDa band will inherently have SEQ ID NO:9. Applicants respectfully submit that since the protein at the 16 kDa band may be CssB *rather* than CssA, it is not inherent that the sequence is SEQ ID NO:9 (which is the sequence for CssA). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is ***necessarily*** present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*,

169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (emphasis added). Since CssA is not necessarily present in the 16 kDa band (as the band could be only CssB), it is not inherent that the sequence of the protein will be SEQ ID NO:9. For this same reason that the 16 kDa band might not be CssA, and because the sequence of CssB was unknown prior to the present invention, the claimed invention directed to purified proteins comprising SEQ ID NO:9 would not have been obvious.

Therefore, Applicants respectfully submit that the claimed invention is novel and unobvious and the rejection under 35 U.S.C. 102(b)/103(a) should properly be withdrawn.

Request for Interview

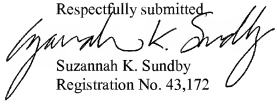
Either a telephonic or an in-person interview is respectfully requested should there be any remaining issues.

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Therefore, it is respectfully requested that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. 1.136(a), and any fees required therefor are hereby authorized to be charged to **Deposit Account No. 210-380**, Attorney Docket No. **034047.033CON4 (WRAIR 95-01D)**.

Respectfully submitted,



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Date: 18 July 2007

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EBI Uniprot UniSave

The UniProtKB Sequence/Annotation Version Archive (UniSave) is a repository of UniProtKB/Swiss-Prot and UniProtKB/TrE versions.

Primary accession number or entry name: P53509 Go!

Date: day-month-year (*e.g.* 30-11-1998 *or* 30-NOV-1998) or year-month-day.

Save UniProtKB P53509 Later >> Back to I

Release: 34.0 Date: 01-OCT-1996

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ID   F6A2_ECOLI     STANDARD;      PRT;   154 AA.
AC   P53509
DT   01-OCT-1996 (REL. 34, CREATED)
DT   01-OCT-1996 (REL. 34, LAST SEQUENCE UPDATE)
DT   01-OCT-1996 (REL. 34, LAST ANNOTATION UPDATE)
DE   CS6 FIMBRIAL SUBUNIT A PRECURSOR (CS6 PILIN).
GN   CSSA.
OS   ESCHERICHIA COLI.
OC   PROKARYOTA; GRACILICUTES; SCOTOBACTERIA; FACULTATIVELY ANAEROBIC RODS;
OC   ENTEROBACTERIACEAE.
RN   [1]
RP   SEQUENCE FROM N.A.
RC   STRAIN=E8775;
RA   WOLF M.K., DE HAAN L.A.M., CASSELS F.C., WILLSHAW G.A.,
RA   GESTEL E.C.M., GAASTRA W., WARREN R., BOEDEKER E.C.;
RL   SUBMITTED (JAN-1994) TO EMBL/GENBANK/DDBJ DATA BANKS.
CC   -!- FUNCTION: FIMBRIAE (ALSO CALLED PILI), POLAR FILAMENTS RADIATING
CC       FROM THE SURFACE OF THE BACTERIUM TO A LENGTH OF 0.5-1.5
CC       MICROMETERS AND NUMBERING 100-300 PER CELL, ENABLE BACTERIA TO
CC       COLONIZE THE EPITHELIUM OF SPECIFIC HOST ORGANS.
CC   ---------------------------------------------------------------------
CC   Copyrighted by the UniProt Consortium, see http://www.uniprot.org/terms
CC   Distributed under the Creative Commons Attribution-NoDerivs License
CC   ---------------------------------------------------------------------
DR   EMBL; U04846; G442381; -.
KW   FIMBRIA; SIGNAL.
FT   SIGNAL        1     18       POTENTIAL.
FT   CHAIN        19    154       CS6 FIMBRIAL SUBUNIT A.
SQ   SEQUENCE   154 AA;  16940 MW;  2D241DFC CRC32;
     MKKTIGLILI LASFGSHART EIATKNFPVS TTISKSFFAP EPRIQPSFGE NVGKEGALLF
     SVNLTVPENV SQVTVYPVYD EDYGLGRLVN TADASQSIIY QIVDEKGKKM LKDHGAEVTP
     NQQITFKALN YTSGEKKISP GIYNDQVMVG YYVN
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